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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,578	03/09/2001	Patrick Hwu	2026-4341	6841

7590 07/08/2002

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EXAMINER
WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
1632	5

DATE MAILED: 07/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/803,578	HWU ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice To Comply* .

DETAILED ACTION

Sequence Listing

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. **The sequences on page 14, lines 13-14, do not have SEQ ID NO.** Applicants must file a "Sequence Listing" accompanied by directions to enter the listing into the specification as an amendment. Applicant also must provide statements regarding sameness and new matter with regards to the CRF and the "Sequence Listing." Applicant is requested to return a copy of the attached Notice to Comply with the reply. Failure to fully comply with the sequence rules in response to the instant office action will be considered non-responsive.

Drawings

2. Fig. 11A and 11F have a hole in the word Fig.

Election/Restriction

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 10-13, 15 and 40-43 drawn to lymphocytes having two receptors, one that is chimeric and recognizes tumor antigen and one that reacts with allogeneic PBL, and methods of making the lymphocytes, classified in class 435, subclass 325.

II. Claims 1-7, 9-14 and 40-43 drawn to lymphocytes having two receptors, one that reacts with a tumor antigen and one that reacts with a viral antigen, and methods of making the lymphocytes, classified in class 435, subclass 325.

III. Claims 16-17, 19-22, 25-29, 31-34, 37-39, drawn to a method of treating cancer using lymphocytes having two receptors, one that is chimeric and recognizes tumor antigen and one that reacts with allogeneic PBL, classified in class 424, subclass 93.1.

IV. Claims 16-18, 20-30, 32-39, drawn to a method of treating cancer using lymphocytes having two receptors, one that is chimeric and recognizes tumor antigen and one that reacts with a viral antigen, classified in class 424, subclass 93.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operations. The mode of operation in Group I is stimulating lymphocytes using allogeneic PBL while Group II is by viral antigens. The lymphocytes of Groups I and II are not used together to treat cancer.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Groups I and III are patentably distinct because the lymphocytes of Group I can be used *in vitro* for assays while administering the lymphocytes to a patient is used for treating cancer. The methods for *in vitro* assays are materially distinct and separate than those required for treating cancer.

Groups I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the lymphocytes of Group I are not stimulated by viral antigen as in Group III. Therefore, the lymphocytes of I cannot be used in the method of III. The lymphocytes of Group I have a different mode of operation than the lymphocytes of Group III.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Groups II and IV are patentably distinct because the lymphocytes of Group II can be used *in vitro* for assays while administering the lymphocytes to a patient is used for treating cancer. The methods for *in vitro* assays are materially distinct and separate than those required for treating cancer.

Groups III and IV are unrelated. The mode of operation of Group III is stimulating lymphocytes using allogeneic PBL while the mode of operation of Group IV is stimulating lymphocytes using viral antigen. The method of Group III is not required for the method of Group IV and the method of group IV is not required for the method of Group III.

The product of Groups I and II do not require transduction in the broad claims while the product used in Groups III and IV require transduction. The product of Groups I and II do not require the method steps of Groups III and IV. Therefore, the scope of search for Groups I and II is different than the scope of search for Groups III and IV. The structure and function of the lymphocytes in Groups I and II are different because the have different receptors having different functions. Therefore, the search required for Group I is not required for Group II. As such, the search required for Group III is not required for the Group IV.

4. This application contains claims encompassing patentably distinct species of the claimed invention. The term "tumor antigen" encompasses numerous antigens disclosed in the specification having different structures and specificity to different tumors (pg 13, 7 lines from the bottom). Applicants must select one of the disclosed tumor antigens.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted. Currently, claims 1-21, 23-33 and 35-42 are generic.

5. This application contains claims encompassing patentably distinct species of the claimed invention. The term "chimeric receptor" encompasses numerous receptors disclosed in the specification having different structures and specificity to different tumor antigens (pg 13, 7 lines from the bottom). Applicant is required under 35 U.S.C. 121 to elect a single disclosed chimeric receptor by describing the structure of the elements making up the chimeric receptor for prosecution on the merits to which the claims shall be restricted. Currently, claims 1-9, 11-24, 26-36 and 38-43 are generic. The chimeric receptor elected should recognize the tumor antigen elected in the species requirement above.

Applicant is advised that a reply to this requirement must include an identification of the species that are elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. If claims

are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

MICHAEL C. WILSON
PATENT EXAMINER